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JUSTICE, ADMINISTRATIVE LAW, AND THE TRANSPLANT CLINICIAN: THE ETHICAL AND LEGISLATIVE BASIS OF A NATIONAL POLICY ON DONOR LIVER ALLOCATION

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INTRODUCTION

Like many other valuable health care resources, the supply of donor livers in the United States is inadequate for the number of patients with end-stage liver disease in need of a liver transplant. The supply-demand imbalance is most clearly demonstrated by the fact that each year approximately ten to twelve percent of liver transplant candidates die before a liver graft becomes available.¹ When such an imbalance between the need for a given health care resource and the supply of that resource exists, some means of distributing the resource must be developed.

As the technique of liver transplantation has evolved over the past forty years, so too has the process by which donor livers are allocated. From its beginnings as an informal, *ad hoc* process, liver graft

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1. Comm. on Organ Procurement and Transplantation Pol'y, Inst. of Med., Organ Procurement and Transplantation: Assessing Current Policies and the Potential Impact of the DHHS Final Rule 2 (1999), *available at*, http://www.nap.edu/catalog.php?record_id=9628#toc.

allocation has since evolved into a formal and somewhat complicated health care policy. This evolution has involved, at various times, discussions between the general public, ethicists, federal legislators, administrative organizations, transplant recipients and transplant clinicians. With the involvement of so many stakeholders, it is increasingly difficult (yet increasingly important) for the transplant clinician to understand the origin of the current U.S. donor liver allocation policy and the process by which such healthcare policies are created. A better understanding of the ethical and legislative foundation of the current policy will prepare the transplant clinician, already well-prepared with a medical and social perspective on organ allocation, as well as those in the public health and legal fields to better contribute to the creation of future allocation policies.

This article first presents an ethical framework for the distribution of donor livers, as this in large part guides the development of policy and legislation. Next, the chronological development of donor liver allocation policies is presented; like many health policies, the development of donor liver allocation policies begins with a series of perceived problems followed by subsequent legislative or policy responses to these problems. This history provides background information essential to understanding the policymaking processes that have produced the current U.S. policies as well as the stakeholders and issues involved in developing these policies. Intermingled with this history are explanations of legislative and policymaking matters aimed at helping clinicians understand the often-confusing and seemingly-foreign processes of health policy. Although this article focuses exclusively on donor liver allocation policy in the U.S., the ethical, legislative, and policy issues raised are relevant to many other public health and medical problems.

An Ethical Framework for Distributing Donor Livers

Ethical principles provide a conceptual framework for all donor liver allocation policies that strive to be fair and morally correct. In the context of donor liver allocation, much of the focus has been on distributive justice, or how scarce resources are distributed to members of a society, and in particular on the concepts of urgency and equity. Also important, however, is the procedural justice of an allocation policy: whether the distribution procedures are, as implemented, fair and accurately reflect what the policies intended. Thus discussion of liver allocation policies should begin with an introduction to these key ethical concepts.

Distributive Justice

Distributive justice refers to the ethical issues surrounding the distribution of resources among members of a society; this includes decisions regarding the type(s) of resources and quantities to be distributed as well as who should receive the resource(s).² Obviously, distributive justice is relevant to medical and non-medical values or resources, but only when the supply of the resource does not meet demand. The potential means of allocating scarce health care resources are many and may include allocation based on need, likelihood of benefit, compliance with medical treatments, ability to pay, social worth, random selection (i.e. lottery), or on a "first come, first serve" basis.³

In 1988 the United Network for Organ Sharing Ethics Committee, a committee composed of physicians, nurses, clergy, ethicists, lawyers and others, was convened "for the general purpose of considering ethical issues related to the process of organ procurement, distribution and transplantation".⁴ Using the 1979 Belmont Report as a starting point,⁵ the committee discussed three key ethical concepts for organ allocation: autonomy, equity, and utility.⁶ Patient autonomy allows candidates to decline a particular organ at any time. Moreover, equity (or justice) describes the idea that organ allocation policies should have "fairness in distribution of the benefits and burdens of an organ procurement and allocation program."⁷ In other words, the distribution of resources should be based on need. In the context of liver transplantation, need has since been determined almost

2. See Robert P. Rhodes, Health Care Politics, Policy, and Distributive Justice 42, 57, 98-120 (1992).

3. See Ingrid Kinkopf-Zajac, Note, *Assessing Patient Compliance in the Selection of Organ Transplant Recipients*, 6 HEALTH MATRIX 503, 521-22, 530-31 (1996).

4. James F. Burdick et al., *Foreword: Principles of Organ and Tissue Allocation and Donation by Living Donors*, 24 TRANSPLANTATION PROC. 2226, 2226 (1992).

5. See Nat'l Comm'n for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979), *reprinted in SOURCE BOOK IN BIOETHICS* 22 (Albert R. Jonsen et al, eds., Georgetown Univ. Press 1998).

6. See *General Principles for Allocating Human Organs and Tissues*, 24 TRANSPLANT PROC. 2227, 2227 (1992) [hereinafter *General Principles*].

7. *Id.* at 2228.

exclusively by medical urgency or likelihood of death if liver transplantation is not performed.⁸

Utility (or efficiency) describes the idea that “an action or practice tends to be right if it results in as much or more aggregate good than any alternative action or practice.”⁹ This concept includes possible obvious medical and social benefits as well as potential harm to the patient after surgery.¹⁰ The primary benefit in the setting of liver transplantation is the prolongation of patient survival. Recently, disease progression has also been discussed as a benefit in situations or disease processes in which patient survival alone does not accurately reflect utility.¹¹ An improvement in quality-of-life is, in general, also a worthy goal to pursue but its importance is secondary to survival.¹² Post-transplant quality-of-life improves significantly in almost all liver transplant recipients, and the magnitude of improvement is not strongly correlated with pre-transplant severity of illness.¹³ This occurrence limits the usefulness of post-transplant quality-of-life as a measure of the benefit of liver transplantation. Nonetheless, when creating allocation policies it is valid to consider other non-survival outcomes or factors that influence survival such as blood group, panel reactive antibody results, history of previous transplant, and candidate age.¹⁴

An allocation process which gives priority to urgency over utility is at least reasonable in the context of liver transplantation in the United

8. *Id.* at 2230.

9. *Id.* at 2227.

10. *See id.* at 2227.

11. Richard B. Freeman, Jr. et al, *Model for End-Stage Liver Disease (MELD) Exception Guidelines: Results and Recommendations from the MELD Exception Study Group and Conference (MESSAGE) for the Approval of Patients Who Need Liver Transplantation with Diseases Not Considered by the Standard MELD Formula*, 12 LIVER TRANSPLANTATION S128, S128 (2006), available at <http://www3.interscience.wiley.com/cgi-bin/abstract/113479106/ABSTRACT> (must register to purchase article).

12. Richard B. Freeman, M.D., Tufts-New England Med. Ctr., Lecture at the 2005 Texas Transplant Society Annual Meeting: Disease Severity Indices and Policy Development: Who Should Come First Anyway? (July 14, 2005) [hereinafter Freeman Lecture].

13. *See* C. Wright Pinson et al, *Health-Related Quality of Life After Different Types of Solid Organ Transplantation*, 232 ANNALS OF SURGERY 597, 597-98, 600-602 (2000).

14. *See generally* *General Principles*, *supra* note 6 (covering the factors that govern survival).

States. An allocation system emphasizing urgency is less reasonable in situations such as kidney transplantation, where dialysis has allowed kidney transplant candidates to achieve long-term survival and severity of renal impairment has little impact on survival. In general, narrowing the range of wait list survival rates or increasing the range of post-transplant survival rates might strengthen the argument for increasing the relative weight of utility in the allocation process, but the accuracy of one's predictive abilities needs to also be considered.

Initially, efficacy was measured in terms of crude post-transplant survival rates, but the focus of efficacy has recently been shifting towards better means of quantifying the additional survival time or "transplant benefit" (often counted in terms of life-years-gained), afforded by liver transplantation. This concept was first introduced in the context of liver transplantation in the mid-1990s, when it was noted that post-transplant survival rates of "electively transplanted" patients were very good, but lower than their waitlist survival would have been without transplantation.¹⁶ These results led some to suggest that less severely-ill candidates should receive priority over more critically-ill candidates.¹⁷ Doctors Robert A. Wolfe and Robert Merion have used more recently-developed quantitative measures of medical urgency to demonstrate that: (a) liver transplantation provides increasing "life years gained" (i.e. survival benefit) for candidates with increasing urgency; and (b) for candidates with stable liver disease, liver transplantation is actually associated with a loss in survival time as compared to remaining on the waiting list.¹⁸

16. See Oscar Bronsther et al., *Prioritization and Organ Distribution for Liver Transplantation*, 271 JAMA 140, 141 (1994); Bijan Eghtesad et al., *Disease Gravity and Urgency of Need as Guidelines for Liver Allocation*, 20 HEPATOLOGY 56S, 58S-59S (1994).

17. See Mark F. Anderson, *The Future of Organ Transplantation: From Where Will New Donors Come, To Whom Will Their Organs Go?*, 5 HEALTH MATRIX 249, 303-04 (1995).

18. See Kim M. Olthoff et al, *Summary Report of a National Conference: Evolving Concepts in Liver Allocation in the MELD and PELD Era*, 10 LIVER TRANSPLANTATION A6, A7-A10 (2004). See generally Robert M. Merion Robert A. Wolfe, et al, *The Survival Benefit of Liver Transplantation*, 5 AM. J. TRANSPLANTATION 307 (2005) (discussing transplant survival benefits for those with pre-transplant risk).

It is becoming increasingly apparent that to accurately evaluate the true efficiency of liver transplantation, such “intent-to-treat” analyses, which apply competing risk analyses, must be used instead of looking at crude survival rates.¹⁹ The use of “intent-to-treat” analyses is conceptually appealing because it incorporates the concepts of maximization of benefit and avoidance of harm—concepts not incorporated by the use of post-transplant survival rates alone. The use of crude survival rates also suggests that there is a trade-off between equity and utility because of the inverse relationship between disease severity and post-transplant survival.²⁰ Discussion of the optimal means of balancing this trade-off previously occupied much discussion in the field.²¹ “Intent-to-treat” analyses largely dispel the idea of such a tradeoff, as the transplant benefit of severely ill liver transplant recipients is large in spite of a slightly lower crude survival rate.²²

Procedural Justice

Once the means by which the allocation of a scarce resource, i.e. the distributive justice, has been agreed upon, methods or procedures must be developed to ensure fair outcomes.²³ Such methods may be referred to as means of achieving procedural justice; developing means to ensure procedural justice may itself be quite a challenge. Consider, for

19. Richard B. Freeman, *Liver Allocation: the Intent-to-Treat Approach*, 19 TRANSPLANT INT'L 270, 270 (2006) (“[W]hen examining organ allocation system, either within center or across nations, their effects on patients must be analyzed using an intent-to-treat approach”) [hereinafter Freeman, *Liver Allocation*]. See also W. Ray Kim et al, *Deaths on the Liver Transplant Waiting List: An Analysis of Competing Risks*, 43 HEPATOLOGY 345, 346 (2006) (discussing death as “failure” with respect towards competing risk analysis).

20. See Francis L. Delmonico et al, *The High-Risk Liver Allograft Recipient*, 127 ARCHIVES SURGERY 579, 584 (1992). See also Sammy Saab et al, *MELD Score Predicts 1-Year Patient Survival Post-Orthotopic Liver Transplantation*, 9 LIVER TRANSPLANTATION 473, 475-76 (2003).

21. See Burdick et al., *supra* note 4, at 2226 (discussing, in 1991, organ sharing and concept of cost and benefit). See generally Daniel Wikler, *Equity, Efficacy, and the Point System for Transplant Recipient Selection*, 21 TRANSPLANT PROC. 3437 (1989) (earlier article using equity and efficiency in choosing transplant recipients).

22. See Freeman, *Liver Allocation*, *supra* note 11, at 272.

23. See generally John Rawls, *A Theory of Justice* (rev. ed., Harvard Univ. Press 1999) (advocating the placement of policy makers behind a “veil of ignorance,” whereby they do not know how the policies they create will affect them later).

example, an employer who is deciding how to distribute monetary awards amongst a group of sales department employees. Employees would likely perceive the distribution of awards based on sales revenue as having distributive justice, and as long as the employer had an accurate means of tallying the sales revenues of each sales person, procedural justice may be achieved. Many factors that affect sales revenue are outside of the control of a salesperson, however, and a decision to distribute the monetary awards based on degree of motivation, rather than sales revenue, may therefore also be perceived as distributive justice; however, there is no well-accepted objective means of measuring motivation, and the procedural justice would be much more difficult to attain in this latter allocation system.

Quantitative scales, also known as “point systems,” are often used as objective means to measure a certain quality. As pointed out by medical ethicist, Professor Daniel Wikler, the point systems used in organ allocation do not, by themselves, promote the distributive justice of an allocation system: while a point system may be objective in its measurement of a given quality, the choice of qualities to be measured and incorporated into an allocation schema remains purely subjective.²⁴

Ad Hoc Donor Liver Allocation: 1968-1984

Progress in the field of liver transplantation made huge strides in the two decades following the first procedurally successful liver transplant at the University of Colorado in 1963.²⁵ Researchers and doctors identified an effective “triple therapy” of immunosuppression drugs,²⁶ defined “brain death,”²⁷ and improved the technical aspects of the liver transplant operation.²⁸ The Consensus Development Conference of

24. See Wikler, *supra* note 21, at 3437.

25. The patient, unfortunately died several months later. Thomas E. Starzl et al, *Evolution of Liver Transplantation*, 2 HEPATOLOGY 614, 614 (1982) [hereinafter Starzl et al, *Evolution*].

26. Thomas E. Starzl, *The Saga of Liver Replacement, with Particular Reference to the Reciprocal Influence of Liver and Kidney Transplantation (1955-1967)*, 195 J. AM. COLL. SURGERY 587, 601-02 (2002) [hereinafter Starzl, *Saga*].

27. See generally Ad Hoc Committee of Harvard Medical School to Examine the Definition of Brain Death, *A Definition of Irreversible Coma*, 205 JAMA 85 (1968) (defining irreversible coma as a new criterion for death); President's Commission for the Study of Ethical Problems in Medicine and Biomedical Behavioral Research, *Guidelines for the Determination of Death*, 246 JAMA, 2184 (1981) (proposing a model statute intended to create nationwide uniformity regarding the determination of death).

28. See generally Starzl, *Saga*, *supra* note 26 (discussing such technical aspects).

1983, initiated by Doctors. Thomas Starzl and Roy Calne, and sponsored by the National Institutes of Health, the Health Care Finance Administration, and the Veterans Administration, concluded that liver transplantation was no longer experimental but rather “a therapeutic modality for endstage liver disease that deserves broader application.”²⁹ In spite of the progress, only five liver transplant centers were active by 1984: the University of Pittsburgh, the University of Minnesota, the University of Tennessee, the University of California at Davis, and the Massachusetts General Hospital.³⁰ With so few active liver transplant centers, the responsibility of procuring and allocating donor livers belonged solely to the transplant clinicians and transplant coordinators at these centers and, without any formal rules or system for allocation in place, was done in an *ad hoc* fashion.³¹ Transplant coordinators had heavy influence over the system; that the process was described as “[a]d hoc case selection at odd hours, guided by the often faulty memory of a transplant coordinator or by incomplete tabular information”³² A toll-free phone number was created to help clinicians treating potential organ donors contact transplant coordinators and help improve donor recovery rates, but procurement remained “decentralized and imperfect”.³³

Federal Legislation: 1984-1985

A Media Blitz

The advent of the drug cyclosporine increased one-year post-transplant survival rates from twenty-four to twenty-nine percent to greater than seventy percent.³⁴ With these improved results, the

29. National Institutes of Health Consensus Development Conference, *National Institutes of Health Consensus Development Conference Statement: Liver Transplantation—June 20-23, 1983*, 4 HEPATOLOGY 107S, 110S (1984).

30. Gina Kolata, *Liver Transplants Endorsed*, 221 Sci. 139, 139 (1983). See also Phil Gunby, *Media – Abetted Liver Transplants Raise Questions of ‘Equity and Decency,’* 249 JAMA 1973, 1973 (1983).

31. Russell H. Wiesner, *Patient Selection in an Era of Donor Liver Shortage: Current US Policy*, 2 NATURE CLINICAL PRAC. GASTROENTEROLOGY & HEPATOLOGY 24, 24 (2005).

32. Thomas E. Starzl et al., *A Multifactorial System for Equitable Selection of Cadaver Kidney Recipients*, 257 JAMA 3073, 3075 (1987).

33. John K. Iglehart, *Transplantation: the Problem of Limited Resources*, 309 NEW ENGLAND J. MED. 123, 126 (1983).

34. Starzl et al, *Evolution*, *supra* note 25, at 621. See also Thomas E. Starzl et al, *Liver Transplantation with the Use of Cyclosporin A and Prednisone*, 305 NEW

demand for liver transplantation increased and soon outgrew the ability of the *ad hoc* allocation process to fairly and effectively procure donor livers and match them to proper candidates. Compounding this difficulty, health insurance plans did not cover the costs of the procedure or the necessary immunosuppressive medications.³⁵ Patients and their families, desperate for resources to help with finding donor livers and funding, turned to the government and to the “vagaries of a [news] media blitz” for help.³⁶

Perhaps the most widely-publicized candidate story was that of Jamie Fiske. Born in 1981, Jamie developed biliary atresia and remained on the waiting list at the University of Minnesota without successfully obtaining a donor liver.³⁷ Jamie’s father, Charlie, began appealing for the directed donation of a pediatric liver, first through Boston-area newspapers, then at a plenary session of the American Academy of Pediatrics, and finally through the major national television networks.³⁸ Within days, the parents of a young trauma victim in Utah directed the donation of their child’s liver to Jamie, who successfully underwent transplantation, in 1982, and was later discharged home.³⁹ Media attention toward liver transplantation continued to build. Several other actors contributed to the media attention on the plight of pediatric liver transplant candidates: Ashley Bailey and Candi Thomas, two infant candidates (the latter the daughter of a White House electrician) gained significant media attention when President Ronald Reagan promised to fly to Pittsburgh by helicopter or by Air Force One if a liver became available.⁴⁰ The media also highly publicized Brandon Hall, a candidate from Tennessee whose mother asked Congress for help in finding a donor liver.⁴¹ President Reagan appealed to the public for donor livers for these “Reagan children” during two consecutive weekly radio

ENGLAND J. MED. 266, 267-68 (1981) [hereinafter Starzl, *Cyclosporin*]; Ry Calne & Roger Williams, *Orthotopic Liver Transplantation: the First 60 Patients*, 1 BRIT. MED. J. 471, 475 (1977).

35. See Iglehart, *supra* note 33, at 128.

36. *Id.* at 123.

37. Phil Gunby, *supra* note 30, at 1973 (1983).

38. See *id.* See also Richard A. Rettig, *The Politics of Organ Transplantation: A Parable of Our Time*, 14 J. HEALTH POL. POL’Y L. 191, 199 (1989).

39. See Gunby, *surpa* note 30, at 1973.

40. See Richard A. Rettig, *The Politics of Organ Transplantation: A Parable of Our Time*, 14 J. HEALTH POL. POL’Y & L. 191, 204 (1989).

41. See *id.* at 199.

addresses in July of 1983, and these pleas were credited with a notable increase in donation rates.⁴²

The National Organ Transplant Act (NOTA)

The media coverage illustrating the plight of candidates and their families, increasing public attention toward liver transplantation, and direct petitioning of legislators by their constituents increased the government's interest in liver transplantation and eventually spurred legislation governing many aspects of allocation.⁴³ In spring of 1983, Democratic House member Al Gore, chairman of the House Science and Technology Subcommittee on Investigations and Oversight, initiated a Congressional inquiry into liver graft allocation and governmental funding of liver transplantation.⁴⁴ The first component of these hearings was an organ procurement workshop convened by Surgeon General C. Everett Koop at the request of President Ronald Reagan and First Lady Nancy Reagan.⁴⁵

The House Energy and Commerce Subcommittee on Health and Environment continued the inquiry into liver transplantation procurement, allocation, and funding in the fall of 1983. Legislative action came when Senator Edward Kennedy proposed a bill that called for the establishment of a national organ procurement and transplantation task force, to look in to the situation.⁴⁶ Gore subsequently introduced House Resolution 4080 in the House of Representatives, which was the National Organ Transplant Act-proper.⁴⁷ Sections of this House bill were then combined with sections of the Kennedy's Senate bill, and reintroduced by Senator Orrin Hatch as S.2048.⁴⁸ The Senate passed this final version in April of 1984 and, after bicameral meetings throughout the summer to negotiate further revisions, the House passed the final version on October 3rd. The final

42. See THOMAS E. STARZL, *THE PUZZLE PEOPLE: MEMOIRS OF A TRANSPLANT SURGEON* 272 (Univ. of Pittsburg Press 2003).

43. See Iglehart, *supra* note 33, at 123-24; Starzl, *Cyclosporin*, *supra* note 34, at 269-70; Robert Pear, *Anecdotes and the Impact They've Had on Policy*, N.Y. TIMES, Dec. 27, 1983, at B6.

44. Iglehart, *supra* note 33, at 123, 124 ; Starzl, *Cyclosporin*, *supra* note 34, at 270; Howard S. Schwartz, *Bioethical and Legal Considerations in Increasing the Supply of Transplantable Organs: From UAGA to "Baby Fae,"* 10 AM. J. L. & MED. 397, 410 (1985).

45. Iglehart, *supra* note 33, at 124, 126.

46. See S. 1728, 98th Cong. (1983).

47. See H.R. 4080, 98th Cong. (1983).

48. Compare S. 2048, 98th Cong. (1983) with S. 1728 and H.R. 4080.

revision of the law: (1) provided funding for regional organ procurement agencies; (2) required the Secretary of the Department of Health and Human Services to establish, by contract, a national organ procurement and transplantation network (OPTN) to facilitate the procurement and distribution of donor organs; (3) mandated Medicare/Medicaid funding of transplant procedures and medication; (4) called for a task force to further study organ allocation; and (5) prohibited the sale of donor organs.⁴⁹ On October 19, 1984 President Reagan signed this revised bill, referred to as the National Organ Transplant Act (NOTA; also referred to as the "Gore bill").⁵⁰

The Legal Authority of NOTA

Unlike the ability to maintain armed forces, regulate international and interstate commerce, coin money, or other powers enumerated in the U.S. Constitution, the ability to regulate organ allocation is not explicitly granted to Congress in the Constitution. Furthermore, any powers not enumerated to the Congress are to remain with the states or with individuals;⁵² safeguarding public health and regulating the practice of medicine are typically considered police powers of the states, not of the federal government.⁵³ Instead, Congress relied on its powers to tax and spend—largely through the Medicare and Medicaid allocations—to encourage compliance with its legislation.⁵⁴ This is perhaps the most common source of authority for Congress's regulation of public health matters.⁵⁵ NOTA in particular was given "teeth" by the passage of the Omnibus Budget Reconciliation Act of 1986 that required all medical centers performing organ transplants to participate in the OPTN or forfeit their eligibility of federal Medicare and Medicaid payments.⁵⁶ Although the voluntary nature of OPTN

49. See National Organ Transplant Act, Pub. L. No. 98-507, 98 Stat. 2339 (1984) (codified as amended at 42 U.S.C. §§ 273-274 (2000)).

50. See *id.*

52. See U.S. CONST. amend. X.

53. See James G. Hodge, Jr., *The Role of New Federalism and Public Health Law*, 12 J.L. & HEALTH 309, 318-23 (1998).

54. See 42 U.S.C. § 1320b-8 (2000).

55. See Wendy E. Parmet, *Health Care and the Constitution: Public Health and the Role of the State in the Framing Era*, 20 HASTINGS CONST. L.Q. 267, 277 & n.46 (1993).

56. See Omnibus Budget Reconciliation Act of 1985, Pub. L. No. 99-507, § 1138 (codified as amended at 42 U.S.C.A. § 1320b-8 (West3002)).

membership is sometimes emphasized,⁵⁷ the prospect of losing federal Medicare/Medicaid payments meant that, for all practical purposes, federal legislation made membership in OPTN, and compliance with HHS-approved OPTN policies, mandatory for U.S. transplant centers that depend on these payments.⁵⁹ A government-appointed task force would later claim that the government had the moral authority to participate in organ allocation because donor organs are not private or market goods but rather a “national resource to be used for the public good.”⁶⁰

Another important feature of NOTA was its rulemaking provisions. Congress typically issues mandates or objectives stated in broad legislative language, then delegates the tasks of creating detailed rules, enforcing the rules, and adjudicating conflicts to an administrative agency. Congress itself does not directly supervise organ allocation. Thus, NOTA delegates specific tasks in the establishment and maintenance of the OPTN to two administrative agents or agencies: (1) the secretary of the Department of Health and Human Services (HHS); and (2) a private non-profit entity that will maintain the OPTN by contract.⁶¹

In the congressional debate that preceded NOTA, in NOTA itself, and in Congressional reports that have followed passage of NOTA, it is clear that Congress intended to keep the creation of specific organ allocation procedures out of the hands of the federal government. A Senate report first demonstrated the objectives in NOTA by stating that the Senate Committee on Labor and Human Resources found “sufficient cause to believe that the national coordinating effort, while stimulated by the federal government and this legislation, should nonetheless be located in the private sector rather than in government.”⁶² NOTA states that with regards to organ allocation

57. See 42 U.S.C. 1320b-8(b)(1) (2000).

59. John A. Sten, Note, *Rethinking the National Organ Transplant Program: When Push Comes to Shove*, 11 J. CONTEMP. HEALTH L. & POL’Y 197, 216 n.172 (1994).

60. Task Force on Organ Transplantation, Dep’t of Health & Human Serv., *Organ Transplantation: Issues and Recommendations* 86 (1986).

61. See *Organ Procurement and Transplantation Network*, 42 C.F.R. pt. 121 (2006).

62. S. Rep. No. 98-382, at 15 (1984), reprinted in 1984 U.S.C.C.A.N. 3975, 3981..

“[t]he Secretary shall *by contract* provide for the establishment and operation of an Organ Procurement and Transplantation Network”⁶³ The House, in a report on legislation that would renew NOTA, subsequently found that “Congress has consistently recognized that the management and formulation of policies applicable to this field of medicine is best left in the expert hands of the medical community, the patients, and donor families who are most directly affected”.⁶⁴ Furthermore, NOTA required only that the OPTN use “medical criteria” in organ allocation procedures;⁶⁵ otherwise, the OPTN may determine the best policies for organ allocation.

Typically authority is delegated to an administrative agency that has either (1) been created by statute (e.g., the Central Intelligence Agency, the National Aeronautics and Space Agency) or that is part of the Executive Branch (e.g., the Environmental Protection Agency, the Department of Defense). NOTA is somewhat atypical – though not unique⁶⁶ – in that Congressional authority is instead delegated to a private party. There has been some legal debate over whether congressional authority can be delegated to a private party such as the OPTN. Although not entirely settled, a large number of cases ranging from *Schechter Poultry Corp. v. United States*⁶⁷ to *Association of American Physicians & Surgeons v. Weinberger*⁶⁸ show support for the delegation of Congressional authority to private parties.

Refining Distributive Justice: 1986-1994

The purpose of NOTA is to facilitate and regulate organ allocation; however, typical of many Congressional statutes, NOTA gave no specific policies or procedures regarding the distribution of donor organs. Instead, NOTA stipulated the creation of a task force to suggest means by which the remainder of NOTA could be implemented. Specifically, the task force was to consider the “medical, legal, ethical, economic, and social issues presented by human organ

63. National Organ Transplant Act, § 372(a).

64. H.R. Rep. no. 106-429, at 9-10 (1999).

65. 42 U.S.C. § 274(b)(2)(B) (2000).

66. Other examples of private parties acting as contractors for the federal government include the National Railroad Passenger Corporation (“Amtrak”) and the U.S. Olympic Committee.

67. See 295 U.S. 495 (1935).

68. 395 F. Supp. 125, 139-40 (N.D.Ill., 1975), *aff'd per curiam*, 423 U.S. 975 (1975).

procurement and transplantation”⁶⁹ As a result, the Task Force on Organ Procurement and Transplantation, a forty-member panel lead by Dr. Olga Jonasson, was convened. This multidisciplinary group met during an eighteen month period from 1984 to April of 1986 and produced several recommendations regarding how donor organs should be procured and allocated.⁷⁰ The Task Force did provide recommendations that were more specific than those in the NOTA legislation regarding how organs should be allocated:

The Task Force recommends that selection of patients both for waiting lists and for allocation of organs be based on medical criteria that are publicly stated and fairly applied . . . [The Task Force also recommends that the] criteria be developed by a broadly representative group that will take into account both need and probability of success. Selection of patients otherwise medically qualified should be based on length of time on the waiting list.⁷¹

In addition, the Task Force recommended that private and public health insurance programs cover the costs of heart and liver transplants and immunosuppression medications (kidney transplants were already covered by most insurance programs at the time).⁷² Finally, the Task Force also recommended that assessments of a candidate’s social worth should not be used in determining priority for organ allocation.⁷³

On October 1, 1986, the first HHS contract to operate the OPTN was awarded to the United Network for Organ Sharing (UNOS). UNOS was originally founded by Dr. David Hume and Dr. Bernard Amos in 1969 as the South-Eastern Regional Organ Procurement Program (SEROPP) and used an early computer to facilitate kidney sharing among transplant centers on the east coast.⁷⁴ SEROPP later gave over its computer system to UNOS, and by the time UNOS was awarded the first OPTN contract, it had grown to support kidney

69. National Organ Transplant Act, § 101(b)(1)(A).

70. Starzl, *Cyclosporin*, *supra* note 34, at 274-75. See also Robert Pear, *Federal Panel Urges U.S. Organ Network and Transplant Aid*, N.Y. TIMES, July 16, 1986, at A1.

71. Task Force on Organ Transplantation, *supra* note 50, at 9-10.

72. See *id.* at 9.

73. *Id.* at 10 (“Selection of patients for transplants not be subject to favoritism, discrimination on the basis of race or sex, or ability to pay.”).

74. See M. Christian Williams et al., *The Organ Center of the United Network for Organ Sharing and Twenty Years of Organ Sharing in the United States*, 77 TRANSPLANTATION 641, 641-42 (2004).

sharing for much of the United States.⁷⁵ UNOS remains a nonprofit entity and has received an HHS contract (typically three years in length) since the first contract was awarded in 1986.⁷⁶

Once the first contract was awarded, UNOS had the task of establishing a procedure for the allocation of organs by a deadline in May of 1987; however, no consensus could be reached by the UNOS organ distribution committee.⁷⁷ To avoid defaulting on its contractual obligations to HHS, UNOS adopted, verbatim, a pre-existing "point system" for liver allocation.⁷⁸ Medical urgency, as defined by functional status, weighed heavily in the system.⁷⁹ ABO compatibility, cytotoxic antibody cross match results, waiting time, distance of the donor and the recipient were also incorporated into the point system.⁸⁰ Initially, donor livers were made available to the local candidate with the highest point total. If there were no suitable local candidates, the donor liver was offered to candidates within the same UNOS region,⁸¹ then to other candidates across the nation. In addition to this system, the UNOS STAT allocation system allowed critically-ill patients with a low likelihood of survival without transplantation to have first access to all donor livers procured throughout the system.⁸² The UNOS STAT category was removed from the allocation system on January 1, 1991, however, amongst allegations that certain medical centers abused the ability to list candidates under UNOS STAT in order to gain further access to donor livers⁸³.

Additional legislation passed during these early years further modified and clarified NOTA. The 1988 Transplant Act Amendments

75. *See id.* at 642-43.

76. *See id.* at 640.

77. *See* Oscar Bronsther, Thomas E. Starzl et al., Letter to the Editor, *In Reply*, 272 JAMA 849, 849 (1994).

78. This allocation schema had been created by Dr. Starzl and his colleagues; it was adopted from his kidney allocation schema that was in use at the University of Pittsburgh at the time. *See id.*

79. Thomas E. Starzl et al., Equitable Allocation of Extrarenal Organs: With Special Reference to the Liver, 20 TRANSPLANTATION PROC. 131, 132 tbl. 3 (1988).

80. *See id.* at 134-36.

81. The United States is divided into 11 UNOS regions. Oscar Bronsther et al., *Prioritization and Organ Distribution for Liver Transplantation*, 271 JAMA 140, 142 (1994).

82. Douglas J. Norman, Letter to the Editor, *The Distribution of Organs for Liver Transplantation*, 272 JAMA 848, 848 (1994).

83. Bronsther et al., *supra* note 81, at 142-43.

required that the HHS Secretary provide public notification of any proposed policy changes and that the Secretary solicit public comments before approval of any proposed policies⁸⁴. In addition, the 1990 Transplant Act Amendments required organs to be distributed "equitably among patients"⁸⁵ and required an assessment of the nation's allocation system to be performed by the Government Accounting Office.⁸⁶ This assessment revealed that some organ procurement organizations were using center lists rather than organ procurement organization-wide lists to allocate organs; this practice, which was recognized as a potential violation of NOTA, was reported to the Secretary of HHS.⁸⁷

Possible Shortcomings in Procedural Justice: 1995-1997

The introduction of tacrolimus and additional refinements in the technique of liver transplantation further improved outcomes. With improved success came improved demand for the procedure, exacerbating the imbalance between donor liver supply and candidate demand. The total number of U.S. liver transplant programs had grown from fifty-eight in 1987 to 112 in 1993.⁸⁸ Yet again, the media brought significant attention to the donor liver allocation process when the legendary baseball great Mickey Mantle became a transplant recipient in June 1995. Although many news sources commented on the conspicuous fact that Mantle received a donor liver within 48 hours of being listed as a candidate (most patients wait for months), no frank misconduct was ever alleged on the part of transplant clinicians at the Baylor University Medical Center in Dallas, where the transplant was performed.⁸⁹ Nonetheless, many suspected that the allocation process was not entirely equitable and that Mantle's celebrity played a role in his short wait.⁹⁰

In November of 1996 UNOS proposed two policy changes: first, using a new scale to better identify the candidates in most urgent need

84. See H.R. Rep. no. 106-429, at 13.

85. See *id.*

86. *Id.* at 39.

87. *Putting Patients First: Resolving Allocation of Transplant Organs J. Hearing Before the Subcomm. On Health and the Environment of the H. Comm. on Commerce and the S. Comm. on Labor and Human Resources*, 105th Cong. 76 (1998) (statement of Sec. Shalala) [hereinafter *Putting Patients First Hearing*].

88. Norman, *supra* note 82, at 848.

89. See Judith Randal, *Mantle's Transplant Raises Delicate Issues About Organ Allocation*, 88 J. NAT'L CANCER INST. 484, 484 (1996).

90. See Randal, *supra* note 89, at 484.

of liver transplantation; and second, giving priority to candidates with acute liver failure, in an attempt to increase emphasis on medical urgency.⁹¹ Rather than using the tiered UNOS score originally proposed by Dr. Starzl, the Child-Turcotte-Pugh (CTP) score was adopted for use in ranking candidates.⁹³ Hospitalization status was combined with the CTP score to categorize patients as UNOS Status 1, Status 2, or Status 3 (in order of decreasing urgency). The UNOS Status was combined with ABO blood type and waiting time to rank candidates for donor organs.⁹⁴ One month after UNOS proposed these changes, HHS held a three-day hearing to discuss these and other issues relevant to donor liver allocation.⁹⁵

CTP-based ranking of candidates had limitations, however. First, the CTP score had not been validated as a predictor of mortality in adult or pediatric liver transplant candidates prior to its use in liver allocation.⁹⁶ Also, subjective components (*viz.* grading of ascites and encephalopathy) introduced more variability into the assessment of urgency than a completely objective scale.⁹⁷ Moreover, waiting time was found to have no significant correlation with waitlist mortality.⁹⁸ Finally, because the ranking of candidates still depended on their hospitalization status, it was susceptible to “unprofessional manipulation”⁹⁹ aimed at prioritizing center interests over candidate interests, as demonstrated by the alleged practices at three Chicago hospitals.¹⁰⁰

91. See Wiesner, *supra* note 31, at 24.

93. Wiesner, *supra* note 31, at 24-25.

94. Theresa L. Heitz & Eric F. Kayira, Note, *Worth Its Weight in Gold: Organ Transplantation and the New UNOS Policies for Allocation of Hearts and Livers*, 30 J. HEALTH & HOSP. L. 195, 197 (1997).

95. Gina Kolata, *Acrimony at Hearing on Revising Rules for Liver Transplants*, N.Y. TIMES, Dec. 11, 1996, at A20.

96. Wiesner, *supra* note 31, at 25.

97. *Id.*

98. Richard B. Freeman & Erick B. Edwards, *Liver Transplant Waiting Time Does Not Correlate With Waiting List Mortality: Implications for Liver Allocation Policy*, 6 LIVER TRANSPLANTATION 543, 549 (2000) (“[W]e found virtually no relation between waiting time and mortality for each medical urgency status, indicating that time on the list is not associated with an increased or decreased risk for death without a transplant.”).

99. Heitz & Kayira, *supra* note 94, at 197.

100. Reuters News Service, *National Briefing, Midwest, Illinois: Prosecutor’s Diagnosis Is Fraud*, N.Y. TIMES, July 29, 2003, at A18.

The OPTN “Final Rule”: 1998-1999

The statement now referred to as the OPTN “Final Rule” (or simply the “Final Rule”) is clearly the single most important development in donor liver allocation policy in the past decade. It is also the most contentious. A discussion of the development of and reaction to the OPTN Final Rule are therefore critical to understanding the recent discussions in donor liver allocation.

When the Congress delegates to an administrative agency the task of filling in the details of a statute or a policy, the agency typically does so through a process termed “rulemaking.” The steps in rulemaking are laid out in the Administrative Procedure Act.¹⁰¹ Most rulemaking is of the “notice and comment” nature,¹⁰² where notice is given through publication in the Federal Register, and comments are submitted by interested parties. This process can have several iterations, and when the agency believes it has no further comments to consider, it publishes its “final rule.”¹⁰³ Following this publication, the rule has the force of law in the same manner as a statute.

Proposal, Debate, Study and Implementation

Several sources report that the HHS discussions that led to the Final Rule were prompted by Jeffrey Romoff, President of the University of Pittsburgh Medical Center.¹⁰⁴ According to these sources, University of Pittsburgh Medical Center Jeffrey Romoff had expressed the University’s frustrations in donor liver allocation matters to David Matter, president of Oxford Development Corporation. Mr. Matter was a “classmate and friend” of President Bill Clinton at Georgetown University and was able to speak to him in person about the issue of organ allocation when Clinton visited Pittsburgh in 1996.¹⁰⁵ Clinton referred the issue to then-Secretary of HHS Donna E. Shalala.¹⁰⁶ On April 2, 1998, HHS issued the OPTN Final Rule.¹⁰⁷ In essence, the Final Rule asked OPTN to develop policies that included three components: (1) minimal listing criteria for waitlist candidates; (2)

101. See 5 U.S.C. § 553 et seq. (2000).

102. See 5 U.S.C. § 564 (2000).

103. See 5 U.S.C. § 551 (2000).

104. Steve Twedt, *Friend Faxes Clinton on Organ Dispute*, PITTSBURGH POST-GAZETTE, Nov. 14, 1996, at C9.

105. See *id.*

106. *Id.*

107. Organ Procurement and Transplantation Network, 63 Fed. Reg. 16,296 (Apr. 2, 1998) (to be codified at 42 C.F.R. pt. 121).

priority given to medical urgency in ranking candidates; and (3) a standardized and objective medical criteria for assessing medical urgency.¹⁰⁸

The transplant community was vocal in its reaction to the Final Rule, and many transplant physicians contacted Secretary Shalala and/or their congressional representatives to voice concerns.¹⁰⁹ The main concern about the Final Rule is fear that compliance would require a single national wait list.¹¹⁰ A national wait list would likely increase the need for cross-country transportation of donor livers, prolonging ischemia times and resulting in the wastage of donor livers, increased retransplantation rates, fewer transplanted candidates and more waitlist deaths. Another concern was that a “sickest first” policy devoid of utility considerations might result in: (1) decreased survival rates, (2) that small community, or rural, based transplant centers would be forced to close, and (3) that there would be a net outflow of donor livers from areas with high donor procurement rates, thus acting as a disincentive to procurement.¹¹¹ Reaction to the Final Rule was not uniformly critical, however, with the American Liver Foundation, Transplant Recipients International Organization, and the National Transplant Action Committee all supporting the Final Rule.¹¹²

In addition to the possible consequences of the policy, many legislators and transplant clinicians were concerned with the perception that HHS was assuming a policy-making role. As detailed above, the original NOTA legislation and all revisions since have delegated to the OPTN the task of developing allocation procedures and required only that they be “based on medical criteria.” The Secretary of HHS was to establish the OPTN by contract but retained oversight over the OPTN and his or her ability to approve OPTN policies.¹¹³ NOTA, however, gave the Secretary no policy or rulemaking authority. Secretary Shalala maintained that the Final

108. See *id.* at 16,296.

109. See *Putting Patients First Hearing*, *supra* note 87, at 65-66 (statement of Rep. Rep. Thurman).

110. See *id.*

111. See FDChEMedia, Inc., *Putting Patients First: Resolving Allocation of Transplant Organs J. Hearing Before the Subcomm. On Health and the Environment of the H. Comm. on Commerce and the S. Comm. on Labor and Human Resources*, 105th Cong. (1998) (testimony of Patient Access to Transplantation Coalition) (testimony not available in officially published report; found in Lexis Nexis CIS).

112. 146 Cong. Rec. H1685 (daily ed. Apr. 4, 2000) (statement of Rep. Stark).

113. See 42 U.S.C. § 273 et seq. (2000).

Rule represented performance goals and a request for the OPTN-initiated policy changes; by itself, she claimed, the Final Rule did not represent policy or an attempt to make policy.¹¹⁴ Yet others claimed that the Secretary's attempt to specify medical urgency as the main priority for allocation and to limit her approval of policies that conformed to the Final Rule constituted attempts at policy making.¹¹⁵

To clarify many of the questions raised by the Final Rule, Congress held a Joint Hearing before the House of Representative's Subcommittee on Health and Environment of the Committee on Commerce and the Senate's Committee on Labor and Human Resources were held on June 18, 1998. Chaired by Representative Michael Bilirakis (R-FL), the Joint Hearings heard testimony from, among others, Donna Shalala; Dr. Ronald Busuttil, then-president of UCLA Medical Center; Dr. Clive Callendar of Howard University; Lawrence Hunsicker, then-President of UNOS; and Dr. Jorge Reyes, then-Director of Pediatric Transplantation Surgery at the University of Pittsburgh Medical Center.¹¹⁶

Included in the Fiscal Year 1999 Omnibus Spending Bill was an amendment that delayed the implementation of the Final Rule by one year and mandated that the Institute of Medicine conduct an independent investigation into the potential effects of the regulation.¹¹⁷ The Institute formed the Committee on Organ Procurement and Transplantation Policy, and after several months of study published a series of recommendations.¹¹⁸ Among them were recommendations to create "organ allocation areas" encompassing regions of nine million people, to use point systems based on medical criteria and not waiting times for candidates classified as Status 2B or Status 3, and for HHS to take more authority over the allocation process.¹¹⁹ After several more

114. See *Putting Patients First Hearing*, *supra* note 87, at 76.

115. See *Putting Patients First Hearing*, *supra* note 87, at 233 (statement of Mr. Nathan, Director, Delaware Valley Transplant Program).

116. See *Putting Patients First Hearing*, *supra* note 87, at II-II, 1.

117. Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, Pub. L. No. 105-277, § 213, 112 Stat. 2681, 2681-359 (1998).

118. Comm. on Organ Procurement and Transplantation Pol'y, Div. of Health Sci. Pol'y, Inst. of Med., *Organ Procurement and Transplantation: Assessing Current Policies and the Potential Impact of the DHHS Final Rule 5* (National Academy Press 1999).

119. See *id.* at 6, 10, 14.

delays, the OPTN Final Rule was implemented within a year of the Institute of Medicine study reflecting the Institute's advice.¹²⁰

Counterattacks to the Final Rule

In addition to the letter-writing campaign and the testimony provided by the community of transplant clinicians, counterattacks designed to thwart implementation of the Final Rule came swiftly and in many forms. Individual transplant centers hired Washington lobbyists to represent their views.¹²¹ Wisconsin governor Tommy Thompson and the Attorney General of Louisiana turned towards legal action in their respective U.S. District Courts, both alleging that Secretary Shalala exceeded her authority in issuing the Final Rule.¹²² Additionally, at least one transplant surgeon was allegedly "blackballed from administrative positions" in the scientific community because of his views on allocation.¹²³

A legislative response to the Final Rule came in the form of a bill, the Organ Procurement and Transplantation Network Amendments of 2000.¹²⁴ The objective of the bill was to require that transplant center-specific data be made publicly-available, to create incentives for organ donation, and to "ensure[] that decision making with regard to organ transplantation remains, as originally intended under [NOTA], in the transplant community".¹²⁵ An amendment added to the bill during the floor debate specifically nullified the Final Rule.¹²⁶ HR-2418 passed the

120. See Organ Procurement and Transplantation Network, 64 Fed. Reg. 56,650, 56,650 (Oct. 20, 1999).

121. Sheryl Gay Stolberg, *Patients' Lives on the Line in Battle Over Transplants*, N.Y. TIMES, Mar. 25, 1998 at A1.

122. See *Wisconsin Governor Challenges Federal Organ Transplant Rules*, CNN, Mar. 15, 2000, <http://archives.cnn.com/2000/HEALTH/03/15/transplant.fight>. See also Sunny Kaplan, *New Federal Organ Transplant Policy Runs Into Resistance*, April 26, 1999, <http://www.stateline.org/live/printable/story?contentId=13668> (last visited April 9, 2007). See also Ronald W. Gimbel, *Tension in the HHS Contracting Regime: A Matter of Life and Death* 18-19, 28 (Rockefeller Col. Rev. Working Paper Series, Paper No. 01-104-01, 2001), available at www.albany.edu/rockefeller/rockreview/issue1/0110101.pdf.

123. Sheryl Gay Stolberg, *Patients' Lives on the Line in Battle over Transplants*, N.Y. TIMES, Mar. 25, 1998, at A1.

124. See H.R. 2418, 106th Cong. (2000).

125. H.R. Rep. No. 106-429, at 9.

126. See 146 Cong. Rec. H1685 (daily ed. Apr. 4, 2000) (statement of Rep. Stark).

House by a 275-147 vote on April 4th, 2000.¹²⁷ Unfortunately, the Senate never took action on the bill.¹²⁸

Other legislative responses to the Final Rule have come at the state level, prohibiting the exportation of donor organs outside the state unless no suitable candidate can be found within the state.¹²⁹ States such as Arizona, Florida, Louisiana, Oklahoma, South Carolina, Texas, and Wisconsin have passed such laws.¹³⁰ The legality of these laws has been questioned.¹³¹ Regardless, such state prohibitions may be counterproductive to the goal of broader organ sharing in an attempt to minimize geographic discrepancies in access to liver transplantation

Case Law and NOTA

Case law involving NOTA has been scant. In one case from the Fifth Circuit of the U.S. Court of Appeals, a defendant was found not to be a federal actor merely because of membership in UNOS.¹³² In *Wheat v. Mass*, Margaret Gordon, a patient with severe liver dysfunction was transferred to Ochsner Hospital in New Orleans to be evaluated for a liver transplantation. There it was determined that she did indeed require transplantation, but because her medical insurance did not cover transplantation, Gordon was told she must raise a \$175,000 down payment.¹³³ Gordon was later placed on the national transplant waiting list but died before an organ match was found.¹³⁴ The appellants sued Mass, a physician at the hospital treating Gordon, and several other parties alleging a number of causes of action.¹³⁵ One of these causes required establishing that Mass' hospital was a federal

127. 146 Cong. Re. H1722 (daily ed. Apr. 4, 2000) (roll call vote no. 101).

128. See Search Results - THOMAS (Library of Congress), <http://thomas.loc.gov/cgi-bin/bdquery/z?d106:HR02418:@@X> (last visited Apr. 17, 2007) (legislative tracking showing H.R. 2418 was never reported out of its Senate committee).

129. Roderick T. Chen, Note, Organ Allocation and the States: Can the States Restrict Broader Organ Sharing?, 49 DUKE L.J. 261, 261, 263 (1999).

130. *Id.* at 263.

131. See generally *id.* (questioning the constitutionality of these state laws under the Commerce Clause).

132. See *Wheat v. Mass*, 994 F.2d 273 (5th Cir. 1993).

133. *Id.* at 275.

134. *Id.*

135. *Id.*

government actor.¹³⁶ The appellants argued that the hospital was such an actor by virtue of its membership in the United Network for Organ Sharing (UNOS).¹³⁷ Citing case law, the Fifth Circuit ultimately found that receiving federal funds by virtue of its participation in UNOS did not make the hospital a federal actor.¹³⁸

In a second case, UNOS was resisting a subpoena issued by the Inspector General of the Department of Health and Human Services. In *U.S. v. United Network for Organ Sharing*, the Inspector General of HHS issued a subpoena to UNOS pursuant to a joint investigation by the Office of Inspector General, the United States Attorney's Office and the Illinois Attorney General "concerning the possible submission to the Medicare and Medicaid programs of false claims for payment by three UNOS member hospitals, including whether such false claims affected the mandated equitable distribution of livers available for transplant."¹³⁹ UNOS, did not want to disclose such information, claiming that having it revealed would impact the integrity of the peer review process involved in the donor program.¹⁴⁰ The IG then sought a subpoena from the district court for these materials.¹⁴¹

After discussing the scope of discovery in federal cases, the court noted that here it was "asked to enforce an administrative subpoena where the court's role is limited because of the important governmental interest in the expeditious investigation of possible unlawful activity."¹⁴² In order to properly weigh the interests involved, the district court used the test set forth in *United States v. Morton Salt Co.* which states that:

[L]aw-enforcing agencies have a legitimate right to [sa]tisfy [*sic*] themselves that corporate behavior is consistent with the law and the public interest . . . [I]t is sufficient if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant.¹⁴⁴

136. Namely, a § 1983 action and a claim under the Fifth Amendment to the U.S. Constitution, both of which required Mass' hospital to be a "state actor" in order to have a viable cause of action. *See id.* at 275-76.

137. *Id.* at 276.

138. *See Wheat*, 994 F.2d at 276.

139. No. 02 C 2295, 2002 WL 1726536, at *1 (N.D. Ill. May 17, 2002).

140. *Id.*

141. *Id.*

142. *Id.* at *2.

144. *Id.* (quoting *United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950)).

Finding such prerequisites, the court then granted the government's petition to have the subpoenas enforced.¹⁴⁵

These two cases cited are the only ones yet to arise from NOTA, but this is a very specific topic of case law, so some analysis is helpful accepting that declaring a trend based on such a small number must be done with prudence. Litigation can be analyzed by looking at what resources are at stake, who is a stakeholder, and how are decisions made in allocating these stakes or resources. NOTA has created a system that changes the way organs are allocated and it changes the way several stakeholders relate to one another.

To forecast trends in NOTA case law, one might first list the kinds of stakeholders affected by NOTA. Largely, these would include recipients of organs, donors of organs, physicians engaged in transplanting organs, UNOS and its members, and HHS. Litigation will arise under NOTA because the supply of organs is far smaller than the need (demand) for these organs and because organs and patients are not fungible. Both of these imbalances require judgment. Dissatisfaction with the outcome of a judgment or the process leading to making of that judgment may, therefore, be followed by litigation.

The Final Rule was attacked in U.S. District Courts by the Governor of Wisconsin and the Attorney General of Louisiana alleging that the Secretary of HHS had exceeded her authority.¹⁴⁶ No case law came from this lawsuit, yet future rule-making by HHS will probably create dissatisfaction among some stakeholders and giving rise to legal challenges.

Although NOTA was enacted to reduce disparities and increase exchange among sources of donors and recipients, most certainly there will be challenges as occurred in *Wheat* will continue. Plaintiffs will allege that improper and impermissible factors were used in deciding who is to get a liver transplant. *Wheat* provides a short but wide-ranging checklist of several US Constitutional and statutory issues that can be expected.

Medical procedures cost money. In the case of organ transplants, a lot of money can be involved. Some of this money will come from the federal government. The federal government has a duty to assure the public that federal funds are used correctly, and it does so through audits. *U.S. v United Network for Organ Sharing* suggest the possibly of a series of cases dealing with such issues as financial audits and the integrity of the peer review process.

145. *Id.* at *1.

146. See Gimbel, *supra* note.122 and accompanying text.

As with most activities involving human decisions and actions, the possibility of litigation grows with increasing numbers of decisions and actions. For now, though, it seems that the purpose of NOTA is being fulfilled with nominal litigation.

Complying with the Final Rule: 2000-Present

In response to the Final Rule's goal of creating rankings with "sufficient number of categories . . . to avoid grouping together patients with substantially different medical urgency,"¹⁴⁷ a subcommittee of the Liver and Intestine Committee of UNOS was formed to identify an improved means of measuring medical urgency.¹⁴⁸ After a review of existing prognostic models, the Mayo End-Stage Liver Disease model, later modified and renamed the Model for End Stage Liver Disease (MELD) was chosen for closer examination because it relied exclusively on objective, easily-obtained clinical parameters.¹⁴⁹ After validation using independent samples of patients with end-stage liver disease, MELD was found to be more accurate in predicting short-term mortality risk than the CTP score.¹⁵⁰ MELD scoring replaced CTP scoring and waiting time as the means of ranking adults on the waiting list on February 26th, 2002; however, allocation still proceeded on a three-tiered system, proceeding from local candidates to regional candidates, then national candidates.¹⁵¹ An evaluation of donor liver allocation since the introduction of MELD

147. 42 C.F.R. § 121.8(b)(2).

148. Russell H. Wiesner et al., *MELD and PELD: Application of Survival Models to Liver Allocation*, 7 LIVER TRANSPLANTATION 567, 567 (2001) [hereinafter Wiesner et al., *MELD and PELD*].

149. See Michael Malinchoc et al., *A Model to Predict Poor Survival in Patients Undergoing Transjugular Intrahepatic Portosystemic Shunts*, 31 HEPATOLOGY 864 (2000); Wiesner et al., *MELD and PELD*, *supra* note 148, at 570-74.

150. Patrick S. Kamath et al., *A Model to Predict Survival in Patients With End-Stage Liver Disease*, 33 HEPATOLOGY 464, 469 (2001) ("In summary, MELD is a reliable measure of short-term mortality risk in patients with end-stage liver disease of diverse etiology and severity."); Wiesner et al., *MELD and PELD*, *supra* note 148, at 570-71, 578 ("Compared to the CTP score . . . the MELD and PELD models provide the means more accurately measure liver disease severity and to better predict which patients are at risk of dying on the waiting list." *Id.* at 578).

151. See Richard B. Freeman Jr. et al., *Improving Liver Allocation: MELD and PELD*, 4 AM. J. OF TRANSPLANTATION 114, 114, 126 (2004).

scoring has demonstrated that a smaller percentage of candidates have been removed from the waitlist because of death.¹⁵²

Despite an improved ability to rank patients based on medical urgency, geographic inequalities in terms of access to liver transplantation still exist.¹⁵³ Reports from two regions suggest that broader sharing, at least for the severely ill Status 1 candidates, contributes to decreased waitlist mortality.¹⁵⁴ In contrast, a computer simulation using an alternative, the UNOS Liver Allocation Model, suggested that broader sharing of donor livers would not significantly impact the annual number of waitlist deaths, post-transplant deaths, or retransplants.¹⁵⁵ More recently, the donor liver allocation schema has been changed to distribute a donor liver to local, regional, and national candidates with MELD scores of 15 and above before offering the liver to local, regional or national candidates with MELD scores below 15.¹⁵⁶ It remains to be seen if this policy change will minimize geographic inequalities in access to liver transplantation.

CONCLUSIONS: LESSONS LEARNED

Good healthcare policy is continually evolving in order to minimize to perceived problems and work towards stated goals. While this

152. See *id.* at 126-27.

153. See generally James F. Trotter & Michael J. Osgood, *MELD Scores of Liver Transplant Recipients According to Size of Waiting List, Impact of Organ Allocation and patient Outcomes*, 291 JAMA, 1871 (2004) (how there is disparity in MELD scores between small and large organ procurement organizations throughout the United States); Randolph L. Schaffer et al., *The Sickest First? Disparities with Model for End-Stage Liver Disease-Based Organ Allocation: One Region's Experience*, 9 Liver Transplantation 1211 (2003) (showing disparity within one UNOS region).

154. See Abhinav Humar et al., *Regionwide Sharing for Status 1 Liver Patients—Beneficial Impact on Waiting Time and Pre- and Posttransplant Survival*, 10 Liver Transplantation 661, 664 (“Nevertheless, despite the biases, there does seem to be a benefit to regional sharing for Status 1 patients.”). See also Kenneth Washburn et al., *Regional Sharing for Adult Status 1 Candidates: Reduction in Waitlist Mortality* 12 Liver Transplantation 470 (2006) (concluding that “regional sharing for status 1 candidates results in an increased transplant rate and a reduction in waitlist mortality.” *Id.* at 470).

155. See Richard B. Freeman, et al., *Redrawing Organ Distribution Boundaries: Results of a Computer-Simulated Analysis for Liver Transplantation* 8 Liver Transplantation 659 (2002) (“The ULAM predicts that changing liver distribution units to larger geographic areas has little positive impact on overall results of liver transplantation in the United States compared with the current plan.” *Id.* at 659).

156. See Freeman Jr. et al., *supra* note 155, at 116-21.

evolution was initially left to transplant clinicians and academicians, the past has shown that the federal and state governments as well as administrative agencies will likely continue to have some role in creating allocation policies. Yet the question remains as to what manner and to what extent should transplant clinicians be involved with these legal actors in the allocation process?

As is evident from the plethora of medical journals cited herein, clinician input is critical to the creation of health policy, as medical expertise is necessary to create specific policies and their implementation. No politician, policy analyst, or lay person will be more familiar with the details of donor organ allocation than the clinicians that are involved in organ allocation on a daily basis. That being said, it should be recognized that the policy-making process, largely political in nature, is qualitatively different from the clinical decision-making process, which is largely based on science. Policy decisions involve tradeoffs and a balancing of interests. While some possible decisions may be inequitable, a solution that will be perceived as best for all stakeholders involved is oftentimes unavailable. As stated by Doctor Douglas Norman, "Until we have enough organs for every waiting patient, *any* organ allocation policy will seem unfair to someone. All national organ allocation policies involve difficult and controversial decisions."¹⁵⁷ Doctor R. Randall Bollinger, a former UNOS president, also expressed this concept when he wrote that "[i]t is clear that no single correct solution exists for liver allocation. A balance of competing objectives and results may be the best available solution."¹⁵⁸ While, the input of transplant clinicians is vital, the input of legislators, policy makers, transplant candidates, and the general public is also important and should also be considered.

Similar to weighing the relative merits of quality and quantity, a discussion of the relative value of utility versus equity is nothing more than an academic endeavor, unless it is grounded in a specific context. The particular details of a given situation must guide policy efforts, and in this respect a donor liver allocation policy is no different. Qualitative results from one survey of adult liver transplant candidates suggests that lay individuals—i.e. those without medical, statistical, or

157. Norman, *supra* note 82, at 848 (emphasis in original).

158. Bollinger RR, *A UNOS perspective on donor liver allocation. United Network for Organ Sharing. LIVER TRANSPL. SURG.* 1995; 1:47-55.
at 52.

160. See Neal R. Barshes et al., *Adult Liver Transplant Candidate Attitudes Toward Graft Sharing Are Not Obstacles to Split Liver Transplantation*, 5 AM. J. TRANSPLANTATION 2047 (2005).

ethical training—can appreciate how the “numbers” might alter the balance between equity and utility.¹⁶⁰ Yet, speaking from personal experience, it is the transplant clinician who can best understand ethical or policy dilemmas in the context of contemporary liver transplantation. In addition, transplant clinicians and clinical researchers possess the expertise needed to properly evaluate the procedural justice of a system. When all the parties involved in the policy-making process have reached consensus on what characteristics or values should be considered and how they should be weighed in the ranking of liver transplant candidates, the task of developing objective and unbiased measures of these characteristics would be best performed by transplant clinicians. Peer-reviewed research, an integral part of contemporary medicine, is an effective means of identifying and developing such measures. Once identified, the transplant clinician community can also be relied upon to effectively implement the use of these measures. The development, validation implementation and frequent re-evaluation of the MELD scoring system provides a good example of how effectively this role can be performed by the transplant clinician community¹⁶¹.

Limits to physician involvement in health policy exist, however. The input of physicians in policy matters is generally perceived by the public as having significant authority, as the input is typically based on science and therefore unbiased by power interests. This authority is weakened, however, when physicians are viewed as stakeholders more concerned with material interests than equitable patient care.¹⁶² As pointed out in a recent editorial, advocacy for a transplant center can often be mistakenly perceived (or disguised) as advocacy for patients.¹⁶³ Likewise UNOS has a dual role: that of being a contractor to the HHS as well as an interest group for transplant clinicians,

161. See, e.g., Kim M. Olthoff et al., *Summary Report of a National Conference: Evolving concepts in Liver Allocation in the MELD and PELD Era*, 10 LIVER TRANSPLANTATION A6 (2003) (discussing the results of a national conference on MELD).

162. See Gimbel, *surpa* note 122, at 18, 24-25.

163. Richard B. Freeman, Jr., Editorial, *Mortality Risk, Behavior, and Pediatric Liver Allocation*, 12 LIVER TRANSPLANTATION 12, 12 (2006) (“[B]ehavior, the compassionate desire to alleviate a child’s disease (or worse, programmatic self-preservation disguised as compassion) drives physicians to utilize the system in favor of their own patients.”).

transplant centers, and organ procurement organizations. Such a role entails an evaluation of competing interests that may sometimes impair its own performance as a whole.¹⁶⁴ Additionally, policymaking is generally considered a task of elected officials, and the participation of scientists and physicians has been criticized as sometimes being too intrusive.¹⁶⁵

While practicing clinicians should factor in creating health policy for specific populations, it can be argued that the predominant role of most physicians is in maximizing the health of individual patients. Withholding a donor organ from a suitable candidate for transplantation for the sake of rationing organs might thus represent a conflict of interest. The act of rationing or distributing scarce healthcare resources is clearly important, but it has been noted¹⁶⁶ that this act would ideally be divorced from the role of providing care by being carried out by separate individuals, minimizing the potential conflict of interest.¹⁶⁷ Although this concept is theoretically appealing, others have noted that it is nearly impossible to divorce the practice of medicine from rationing decisions.¹⁶⁸

Finally, transplant clinicians and legislators should consider two additional ideas in light of the development of the current liver allocation policies. First, legislation is typically passed in response to perceived problems or disparities. Legislative efforts that led to NOTA were stimulated at least in part by the absence of a formal procedure to distribute donor organs and the resulting problems.

164. See Gimbel, *supra* note 122, at 19-20.

165. See SHEILA JASANOFF, *THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS* 178-79 (Harvard Univ. Press 1990) (in discussing FDA deliberations, it is noted that “[p]urists might object that the blending of science and policy in advisory proceedings cedes too much political control to the experts, undermining the agency’s accountability.” *Id.* at 178.).

166. See MARK A. HALL, *MAKING MEDICAL SPENDING DECISIONS: THE LAW, ETHICS, AND ECONOMICS OF RATIONING MECHANISMS* 114-15, 118 (Oxford Univ. Press 1997).

167. Bollinger, *supra* note 158, at 54 (“Problems have arisen when the same person who is doing the best for his or her patients(s) is also making decisions on the allocation of scarce resource . . . Physicians must be able to step back from their roles as advocates for individual patients and look critically at allocation issues apart from their own patients and centers.”).

168. Robert D. Truog et al., *Rationing in the Intensive Care Unit*, 34 *CRITICAL CARE MED. J.* 958, 959 (2006) (“Although agreeing that many types of rationing should be done through public policy and regulatory structures, we believe that no bright line can be drawn that will protect the bedside clinician from the need to make rationing decisions.”).

During the 1998 Congressional hearings on the Final Rule, HHS Secretary Donna Shalala intimated that the Final Rule was issued because the transplant community had failed to address inequities in the allocation system that had been identified several years earlier.¹⁶⁹ Transplant clinicians may therefore limit further legislative or administrative involvement in the liver allocation process by preemptively acting to correct any perceived problems with allocation policies. It would therefore be worthwhile for those involved in the issue in the legal community to recognize and allow such action by the medical community.

Second, the news media publicity generated by the “Reagan children” of 1984 and by Mickey Mantle’s liver transplant in 1995 clearly demonstrate that anecdotes can significantly impact public policy and legislative processes.¹⁷⁰ While descriptive statistics, clinical trials and mathematical models have much more credibility with those in the scientific and medical communities, anecdotes can illustrate the real-life effects of health policy or medical practices on individuals. Furthermore, anecdotes are a common vehicle used by news media sources to explain problems; they are often compelling and require little formal training to understand. At the Congressional hearings convened to discuss the Final Rule, the testimony of transplant physicians opposed to the Rule contained notably few anecdotes.¹⁷¹ In contrast, many of the non-physicians in favor of the Rule provided testimony that featured or consisted almost entirely of anecdotes.¹⁷² Transplant clinicians and professional organizations may therefore want to consider the use of anecdotes to better illustrate or explain allocation-related problems to the general public, federal legislators and administrative agencies.

In conclusion, the system of donor liver allocation in the U.S. is a constantly evolving health policy. Organ allocation is guided by an ethical foundation, of which equity (need) and utility (likelihood of

169. See *Putting Patients First Hearing*, *supra* note 87, at 76 (statement of Sec. Shalala).

170. See Pear, *Anecdotes and the Impact They’ve Had on Policy*, *supra* note 43, at B6.

171. *Putting Patients First Hearings*, *supra* note 87, at 135-45, 194-97, 211-15, 220-23 (statements of Dr. Hunsicker, President, UNOS; Mr. Busutil, Chief, Division of Liver and Pancreas Transplantation, UCLA School of Medicine; Dr. Ramos, Director, Liver Transplantation, Lifelink Transplantation Institute; Dr. Reese, Surgeon, University of Vermont respectively).

172. See *id.* at 56, 57-58 (statements of Sen. Torricelli & Sen. Kerrey respectively).

benefit) are the most important considerations. Legislation has also had an increasingly important role in the organ allocation process. Federal legislation prior to 1998 allowed the transplant community to determine the best balance of equity and utility, but more recent legislation has given more weight to urgency in ranking candidates and has wrested some of the decision-making from clinicians. Indeed, decisions regarding the distributive justice of donor liver allocation schemas are not exclusively medical, and thus should include input from transplant candidates, politicians, policy makers, general public and transplant clinicians alike. Future challenges include developing policies that minimize geographic disparities in access to liver transplantation and reconciling state limitations on organ sharing with federal legislation and policy goals. Appreciation of both the ethical and legislative foundation for allocation policies would improve the ability of physicians to participate with legislative actors in the creation of such policies. In the end, donor liver allocation is not exclusively medical, ethical, or political in nature, but rather a combination of all three.